Valoate®

Sodium Valproate BP

COMPOSITION

Valoate® Syrup: Each 5 ml syrup contains Sodium Valproate BP 200 mg.

Valoate® CR 200 tablet: Each controlled release tablet contains a mixture of Sodium Valproate BP & Valproic acid BP equivalent to 200 mg Sodium Valproate.

Valoate® CR 300 tablet: Each controlled release tablet contains a mixture of Sodium Valproate BP & Valproic acid BP equivalent to 300 mg Sodium Valproate.

Valoate® CR 500 tablet: Each controlled release tablet contains a mixture of Sodium Valproate BP & Valproic acid BP equivalent to 500 mg Sodium Valproate.

PHARMACOLOGY

The active ingredient of Valoate® is Sodium Valproate which shows antiepileptic properties in various types of seizures. The exact mechanism of Valoate® (Sodium Valproate) is not yet established. However it is suggested that its activity is related to increased brain levels of Gama Amino Butyric Acid (GABA).

INDICATION

Valoate® is indicated for -

Epilepsy: All types of epilepsy such as Absence seizure, Myoclonic seizure, Tonic-clonic seizure, Atonic, Mixed, simple or generalized, Secondary generalized seizure etc.

Mania: For the treatment of manic episodes of bipolar disorders.

Other: As an alternative treatment for febrile convulsion & migraine prophylaxis.

DOSAGE & ADMINISTRATION

Adults:

Initial: 600 mg/ day in 2 divided doses, preferably after food. Dose may be increased by 200mg/day at 3 days interval to a maximum of 2.5 gm daily in divided doses until control of seizure is achieved.

Maintenance dose: Usually 1-2 gm daily (20-30 mg/ kg daily).

Children (up to 20 kg):

Initial: 20 mg/ kg daily in divided doses. Dose may be increased in severe cases with proper monitoring of plasma concentration.

Children (over 20 kg):

Initial: 400mg/ day (irrespective of weight). Dose may be increased by 20-30 mg/ kg if required to achieve control.

CONTRAINDICATION

Sodium Valproate is contra-indicated in patients with known hypersensitivity of Sodium Valproate, personal or family history of severe active liver disease, hepatic dysfunction, porphyria and known urea cycle disorder.

WARNINGS & PRECAUTION

Liver function should be monitored before therapy and during first six months, especially in those patients who seem most at risk. Blood tests are recommended before surgery. Renal impaired patients, pregnant and brest feeding mother should be specially cared.

Valproate is eliminated mainly through the kidney, partly in the form of ketone bodies which may lead to false statement in urine ketone test.

Sudden withdrawal of therapy should be avoided.

SIDE EFFECT

Gastric irritation, nausea, ataxia & tremor; hyperammonaemia, increased appetite & weight gain; transient hair loss, oedema, thrombocytopenia, and inhibition of platelet aggregation, impaired hepatic function leading rarely to fetal hepatic failure; rashes; sedation; rarely lethargy and confusion and also increased alertness; rarely pancreatitis, leucopenia, pancytopenia, red cell hypoplasia, fibrinogen reduction; irregular periods, amenorrhoea, gynaecomastia, toxic epidermal necrolysis, hearing loss, Fancoli's syndrome, dementia, Steven's-Johnson syndrome, and vasculitis have also been reported.

DRUG INTERACTIONS

Sodium Valproate is a non specific inhibitor of drug metabolism. Phenobarbital, Phenytoin, Warfarin, Aspirin etc. interacts with Sodium Valproate.

PREGNANCY & LACTATION

Sodium Valproate crosses the placenta in humans which may lead to neural tube defects such as anencephaly and spina bifida if exposed in the first trimester.

Sodium Valproate may excrete in breast milk. So treatment with Sodium Valproate may cause harm to new born baby.

STORAGE

Valoate® Syrup: Store below 30^0C, protected from light.

Valoate® CR tablet: Store below 30^0C, protected from light.

Keep all medicines out of the reach of children.

HOW SUPPLIED

Valoate® Syrup: Each box contains a PET bottle with100 ml syrup & a measuring cup.

Valoate® CR 200 tablet: Box containing 50 tablets in blister pack.

Valoate® CR 300 tablet: Box containing 50 tablets in blister pack.

Valoate® CR 500 tablet: Box containing 30 tablets in blister pack.

Manufactured by :

SQUARE

PHARMACEUTICALS LTD.

BANGLADESH

Revision No.: 01